

What is claimed is:

1 Claim 1. A device for generating a flow of a mixture of a selected drug and a
2 gaseous potentiating substance for administration to an individual comprising:

3 a container for pressurized holding of the gaseous potentiating substance, defining
4 an opening sealed with a cap;

5 a head adapted for attachment to the container, said head defining a chamber
6 wherein when the head is attached to the container the opening is within the chamber and
7 wherein the opening and cap are axially translatable to various positions within the
8 chamber, a plenum, an exit passage and at least one outlet, wherein the plenum is
9 connected to the outlet by means of the exit passage, said exit passage forming a venturi
10 region near the outlet, and wherein the chamber selectively communicates with the
11 plenum by means of a valve, said valve biased to a closed position; said head further
12 comprising a reservoir adapted for holding an aspiratable agent that contains the drug and
13 a capillary passage connecting the reservoir and the venturi region of the exit passage;
14 and said head further including a dispensing region near the outlet adapted for applying a
15 discharge from the outlet to a facial orifice of the individual; and

16 a needle adapted for perforating the cap, said needle attached to the valve and
17 positioned such that the needle perforates the cap when the opening and cap are in a first
18 preselected position within the chamber and forms an orifice of a desired size; and such
19 that when the opening and cap are in the first preselected position, the needle seals the
20 orifice and the valve is forced open;

21 a lock for holding the opening and cap in a second preselected position within the
22 chamber wherein the needle is at least partially removed from the orifice and the valve is
23 closed, whereby the chamber is filled with the gaseous potentiating substance at a high
24 pressure;

25 a first spring for moving the opening and cap relative to the chamber to the first
26 preselected position when the lock is released, whereby the gaseous potentiating
27 substance moves from the chamber to the outlet, passing through the plenum and the

28 venturi region of the exit passage, and aspirating a selected amount of the agent,
29 discharging a mixture of the agent and the gaseous potentiating substance at the outlet.

1 Claim 2. The device of claim 1 wherein the dispensing region is adapted to apply
2 the discharge to a nostril of the individual.

1 Claim 3. The device of claim 1 wherein the dispensing region is adapted to apply
2 the discharge to the individual's mouth.

1 Claim 4. The device of claim 1 further comprising:
2 a collar adapted to be fixedly attached to the container, wherein the head is
3 simultaneously attachable to the container and the collar.

4 Claim 5. The device of claim 4 wherein the container defines a region near the
5 opening and cap that is substantially cylindrical and that defines a first set of screw
6 threads, the collar defines a substantially cylindrical aperture that further defines a second
7 set of screw threads adapted to mate with the first set of screw threads and also defines a
8 third set of screw threads; and the head defines a fourth set of screw threads adapted to
9 mate with the third set of screw threads, and further includes a gasket adapted to seal the
10 head to the container.

1 Claim 6. The device of claim 1 wherein the first preselected position may be
2 selected and modified by the user.

1 Claim 7. The device of claim 5 wherein the first preselected position may be
2 selected and modified by the user.

1 Claim 8. The device of claim 7 wherein the first preselected position may be
2 modified by rotably adjusting the collar to the selected location along the central axis of

3 the container such that the valve is open to a desired amount when the opening and cap
4 are in the preselected first position relative to the head and wherein the collar further
5 includes a set screw adapted for holding the collar at the selected location.

1 Claim 9. The device of claim 7 wherein the collar further includes markings
2 corresponding to a range of possible first preselected positions.

1 Claim 10. The device of claim 8 wherein the collar further includes markings
2 corresponding to a range of possible first preselected positions.

1 Claim 11. The device of claim 1 wherein the container holds the gaseous
2 potentiating substance at approximately 60 atmospheres and the volume of the chamber
3 is between .07 and .33 cc.

1 Claim 12. The device of claim 1 wherein the valve is biased closed by a second
2 spring.

1 Claim 13. The device of claim 1 further including a sleeve forming an opening and
2 positioned in the venturi region of the exit passage; said sleeve axially translatable within
3 the exit passage and operationally connected to the valve such that movement of the
4 valve to an open position simultaneously moves the opening to be aligned with the
5 capillary passage.

1 Claim 14. A method for controlling the effect of a drug on an individual comprising:
2 Administering the drug;
3 Generating a flow of a gaseous physiologically active agent; and
4 *a* Infusing at least one facial orifice of the individual with the gaseous
5 physiologically active agent to enhance the action of the drug.

1 Claim 15. A method as in claim 14, wherein the orifice is selected from the group
2 consisting of: at least one eye, at least one ear, at least one nostril and a mouth.

3 Claim 16. A method as in claim 14, wherein the gaseous physiologically active agent is
4 selected from the group consisting of carbon dioxide, nitric oxide, nitrous oxide, oxygen,
5 helium, dilute mixtures of nitric oxide, and isocapnic mixtures of acid gases.

1 Claim 17. A method as in claim 14, wherein the orifice is selected from the group
2 consisting of a nostril and a mouth, and wherein the individual substantially inhibits the
3 passage of the gaseous physiologically active agent into the trachea and lungs by limiting
4 inhalation of the gaseous physiologically active agent.

1 Claim 18. A method as in claim 14, wherein the infusing step is performed after the
2 administering step.

1 Claim 19. A method as in claim 14, wherein the infusing step is performed coincident
2 with the administering step.

1 Claim 20. A method as in claim 14, wherein the infusing step is performed before the
2 administering step.

1 Claim 21. A method as in claim 17, wherein the infusing step is performed after the
2 administering step.

1 Claim 22. A method as in claim 17, wherein the infusing step is performed coincident
2 with the administering step.

1 Claim 23. A method as in claim 17, wherein the infusing step is performed before the
2 administering step.

1 Claim 24. A method as in claim 17, wherein both a nostril and a mouth are
simultaneously infused.

1 Claim 25. A method as in claim 17, wherein both nostrils are simultaneously infused.

2 Claim 26. A method as in claim 18, wherein the infusing step further includes the
3 individual inhaling the gaseous physiologically active agent.

4 Claim 27. A method as in claim 14 wherein the gaseous physiologically active agent is
5 carbon dioxide and the infusing step further includes the individual inhaling the carbon
dioxide simultaneously with ambient air and the generating step further includes
generating a flow of the carbon dioxide at a rate sufficient to produce a concentration of
the carbon dioxide of between approximately 6% to 10% during inhalation.

1 Claim 28. A method as in claim 15 comprising at least one additional infusing step.

1 Claim 29. A method as in claim 14, wherein the gaseous physiologically active agent is
2 diluted with air.

1 Claim 30. A method as in claim 14, further comprising the steps of:

2 Mixing the preselected amount of the drug and a preselected amount of
3 the gaseous physiologically active agent to form a combination;

4
5 wherein the generating, administering and infusing steps occur substantially
6 simultaneously and immediately after the mixing step; and the generating step further
7 comprises generating a flow of the combination of the gaseous physiologically active
8 agent and the drug.

1 Claim 31. A method as in claim 30, wherein the administering step further comprises
2 inhaling the mixture of the gaseous physiologically active agent and the drug.

1 Claim 32. A method as in claim 14 wherein the gaseous physiologically active agent
2 is a gas.

1 Claim 33. A method as in claim 14 wherein the gaseous physiologically active agent
2 is a vapor.

1 Claim 34. A method as in claim 14 wherein the infusing step further includes the
2 individual inhaling the gaseous physiologically active substance simultaneously with
3 ambient air and the generating step further includes generating a flow of the gaseous
4 physiologically active substance at a rate sufficient to produce a preselected
5 concentration of the gaseous physiologically active substance during inhalation.

1 Claim 35. A method as in claim 14 wherein the gaseous physiologically active agent is
2 carbon dioxide and the infusing step further includes the individual inhaling the carbon
3 dioxide simultaneously with ambient air and the generating step further includes
4 generating a flow of the carbon dioxide at a rate sufficient to produce a concentration of
5 the carbon dioxide of between approximately 5% to 70% during inhalation.

1 Claim 36. A device for generating a controlled flow of gas from a pressurized gas
2 container that forms an opening sealed with a cap and having a known internal pressure
3 comprising:

4 a head adapted for attachment to the container; said head forming an interior
5 chamber and at least one outlet in communication with the interior chamber through an
6 exit passage; wherein, when the head is attached to the container, the opening is within
7 the chamber and wherein the opening and cap are axially translatable within the chamber;

8 a needle attached to the head and positioned in the chamber and adapted for
9 perforating the cap when the opening and cap are at a preselected position in the
10 chamber to form an orifice of a preselected diameter in the cap, and wherein the needle is
11 axially translatable; a spring engaged with the needle that holds the needle in the orifice;
12 and a lever for actuating the needle such that operation of the lever lifts the needle from
13 the orifice and compresses the spring, whereby gas from the pressurized container is
14 released through the outlet.

1 Claim 37. The device of Claim 36 wherein that portion of the container near the
2 opening is substantially cylindrical and defines a first set of screw threads and the interior
3 chamber includes second set of screw threads adapted for mating with the first set of
4 screw threads.

1 Claim 38. The device of Claim 36 wherein the needle comprises:
2 a needle body having a penetrating tip and a proximal conical shaft with a first
3 region near the penetrating tip and a second region removed from the penetrating tip, and
4 wherein the orifice is formed by the penetrating tip and enlarged to a selected diameter
5 by the second region of the conical shaft; and
6 wherein the first region of the conical shaft defines a taper angle of greater than
7 25° and the second region of the conical shaft defines a taper angle of between 2° and 6°.

1 Claim 39. The device of claim 36 wherein the exit passage further includes a venturi
2 region and the head further forms an air inlet passage communicating between the
3 ambient atmosphere and the venturi region.

1 Claim 40. A dispenser as in claim 36 wherein the diameter of the orifice is selected
2 to provide a maximum flow of between approximately 100 and 400 cc/sec of gas.

1 Claim 41. A flow regulator, adapted for attachment to a container of pressurized gas
2 that forms an opening sealed with a cap, for providing a flow of therapeutic gas to a
3 individual comprising:

4 a head, a tubular sleeve having a first end and a second end, and a tubular
5 collar; wherein

6 the collar is adapted for fixed attachment to the container adjacent to and
7 surrounding the opening and cap and defines a first set of external screw threads;

8 the head defines a first and second end with an outlet at the first end and
9 an exit passage between the outlet and the second end of the head, and wherein the
10 second end of the head is adapted to be placed adjacent to the cap and defines a second
11 set of external screw threads;

12 the head and collar are connected to allow axial translation of the head relative to
13 the collar and container and to prevent rotational movement of the head relative to the
14 collar and container; and

15 the tubular sleeve defines a third set of screw threads at the first end adapted to
16 mate with the first set of screw threads and a fourth set of screw threads at the second end
17 adapted to mate with the second set of screw threads; and wherein the first and third sets
18 of screw threads are slightly coarser than the second and fourth sets of screw threads and
19 the head further includes:

20 a needle fixed to and extending from the second end of the head, said needle
21 adapted for perforation of the cap when the cap and the second end of the head are at a
22 preselected distance from each other and further adapted to form and seal an orifice of
23 selected size at preselected distances of cap penetration, such that partial removal of the
24 needle permits a flow of gas from the orifice in an amount related to the distance the
25 needle is removed;

26 whereby when the screw threads are mated, the flow regulator is attached to the
27 container and the orifice is formed by the needle, the amount of gas flow from the outlet
28 may be selected by rotating the sleeve to effect the axial translation of the head and
29 needle.

1 Claim 42. A flow regulator as in claim 41 wherein the head further includes a detent,
2 whereby the rotation of the sleeve and the axial translation of the head and needle may be
3 adjusted to preselected positions.

1 Claim 43. A flow regulator as in claim 41 wherein the sleeve and collar include
2 indicator markings.

1 Claim 44. A flow regulator as in claim 41 wherein the collar includes indicator
2 markings for showing the relative position of the collar and the container whereby the
3 amount of maximum needle penetration, the orifice size and the maximum flow rate are
4 indicated; and the sleeve includes indicator markings for showing the relative position of
5 the sleeve and the collar whereby the distance the needle has been removed from the
6 orifice and the percentage of maximum flow rate may be determined.

1 Claim 45. A flow regulator as in claim 42 wherein the collar includes indicator
2 markings for showing the relative position of the collar and the container whereby the
3 amount of maximum needle penetration, the orifice size and the maximum flow rate are
4 indicated; and the sleeve includes indicator markings for showing the relative position of
5 the sleeve and the collar whereby the distance the needle has been removed from the
6 orifice and the percentage of maximum flow rate may be determined.

Sub
1 A5 } Claim 46. The method of claim 14 wherein the gaseous physiologically active agent
2 B1 is vasoactive.

1 Claim 47. The method of claim 14 wherein the gaseous physiologically active agent
2 is neuroactive.

- 1 Claim 48. The method of claim 14 wherein the gaseous physiologically active agent
- 2 is myoactive.

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